REMARKS

Applicants have canceled claims 1-20 and added substitute claims 21-35 to better define the claimed invention. Applicants respectfully submit that no new prohibited matter has been introduced by this Preliminary Amendment. While written description support for the claims can be found throughout the specification, specific support for these new claims can be found as indicated in the following chart.

Claim No.	Support in Specification
21	page 13, lines 15-20; original claim 1
22	page 14, lines 11-13; original claim 8
23	page 12, lines 14-15
24, 32	page 14, lines 13-14
25, 33	page 14, lines 14-15
26, 34	page 12, line 24; page 14, lines 16-17
27, 35	page 12, line 24; page 14, lines 17-18
28, 29	page 44, lines 16-20
30	page 49, lines 18-20
31	page 12, lines 23-27; original claim 17

I. Summary of the Office Action dated July 18, 2000

1. Claim 1 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 21 of copending U.S. Patent Application 08/980,394.

2. Claim 1 was rejected under 35 U.S.C. § 102(b) as being anticipated by DeBin *et al.*, (1993) Am. J. Physiol. 264, C361-369.

3. Claims 1 and 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over DeBin et al., (1993) in view of Hammock *et al.*, (1998) U.S. Patent 5,756,340 in further view of Hosli *et al.*, (1990) Exp. Brain Res. 80, 621-625.

4. No claims were allowed.

II. Response to the obviousness-type double patenting rejection

Applicants have canceled claim 1 in the present application and claim 21 in U.S. Patent Application 08/980,394 and therefore submit that the rejection is moot. Applicants further submit that the obviousness-type double patenting rejection does not apply to the new claims in either application because the new claims in the present application are directed toward pharmaceutical compositions while the new claims in U.S. Patent Application 08/980,394 are directed toward methods of treatment.

III. Response to the rejection under 35 U.S.C. § 102(b)

Applicants have canceled claim 1 and further submit that new claim 21 and its dependent claims are not anticipated by DeBin *et al.*, (1993) because this reference does not disclose a pharmaceutical composition comprising a pharmaceutically acceptable carrier. The purified chlorotoxin produced by DeBin *et al.*, (1993) was reconstituted in 10 mM trifluoroacetic acid (see page 363, column 2, fifth paragraph) prior to dilution in water to a final volume of only 10 µl (see page 363, column 2, third paragraph). Respectfully, a composition with such a high concentration of trifluoroacetic acid as in the DeBin *et al.*, (1993) reference is not a pharmaceutical composition and does not anticipate the pending claims.

Also, the chlorotoxin composition administered to the arthropods in the acute toxicity experiments conducted by DeBin *et al.*, (1993) contained impurities (see Figure 1B (inset)). Specifically, two additional peaks were isolated in the large peak from which the fractions were collected. These peripheral peaks were later determined not to have any activity and thus were

identified as major contaminants of the chlorotoxin material isolated using the aforementioned purification method (see page 366, column two, second paragraph). Certainly, a composition containing such unknown impurities is not a pharmaceutical composition and does not anticipate the pending claims.

Applicants will be submitting in due course a declaration under 37 C.F.R. § 1.132 by Dr. Howard Levine, an expert in this field, indicating that the chlorotoxin compositions disclosed by DeBin *et al.*, (1993) do not constitute pharmaceutical compositions for the reasons discussed above.

IV. Response to the rejection under 35 U.S.C. § 103(a)

Applicants have canceled claims 1 and 4 and therefore submit that the rejection is moot. Applicants maintain however, that new claims 21-35 are not obvious in light of the combined teachings of the cited references. Applicants maintain that DeBin *et al.*, (1993) does not teach a pharmaceutical composition. Furthermore, this reference teaches administration of a chlorotoxin composition to arthropods to confirm the lethal effects of chlorotoxin.

In a similar manner, Hammock *et al.*, (1998) and Hosli *et al.*, (1990) do not teach a pharmaceutical composition as set forth in the claims. The Office Action indicates that Example 6 of Hammock *et al.*, (1998) teaches a labeled chlorotoxin composition (page 4, line 11). Applicants respectfully submit that the Hammock *et al.*, (1998) composition also comprises thirty percent solvent B, this solvent containing fifty percent acetonitrile (column 11, lines 54-57). Applicants respectfully submit that the presence of acetonitrile in the composition renders it unacceptable for human administration and that Hammock *et al.*, (1998) do not produce a pharmaceutical composition with a pharmaceutically acceptable carrier as required by the pending claims.

The Office Action further indicates that Hosli *et al.*, (1990) teaches a composition comprising a radiolabeled chloride channel ligand for *in vitro* receptor localization and detection

of chloride channels (page 5, line 1). Applicants respectfully submit that Hosli *et al.*, (1990) disclose chloride channel ligands radiolabeled with tritium. Again, the compositions are not pharmaceutical compositions because the extended half-life of tritium makes it unsuitable for human administration. Applicants therefore respectfully maintain that none of the cited references, when viewed alone or in combination, teaches nor provides the motivation to one skilled in the art to produce a pharmaceutical composition comprising chlorotoxin and a pharmaceutically acceptable carrier as required in the pending claims.

V. Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims. A favorable action is awaited.

Should the Examiner find that an interview would be helpful to further prosecution of this application, he is invited to telephone the undersigned at his convenience.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted
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